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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/477,392 | 01/04/2000 | NICHOLAS H. HEINTZ | V0139/7038-(HCL) | 9183 |

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HELEN C LOCKHART
WOLF GREENFIELD & SACKS P C
600 ATLANTIC AVENUE
BOSTON, MA 02210

[REDACTED] EXAMINER

ZEMAN, ROBERT A

| ART UNIT | PAPER NUMBER |
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| 1645 | LO |

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Please find below and/or attached an Office communication concerning this application or proceeding.

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|--|--|------------------|--|---|--|
| Office Action Summary | Application No. | Applicant(s) | | | |
| | 09/477,392 | HEINTZ ET AL. | | | |
| | Examiner Robert A Zeman | Art Unit 1645 | | | |
| -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- | | | | | |
| <p>Period for Reply</p> <p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| <p>Status</p> <p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>18 April 2002</u>.</p> <p>2a)<input type="checkbox"/> This action is FINAL. 2b)<input checked="" type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p> | | | | | |
| <p>Disposition of Claims</p> <p>4)<input checked="" type="checkbox"/> Claim(s) <u>1-6,8-23 and 29</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) <u>17 and 23-29</u> is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>1-6, 8-16</u> is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) <u>1-6,8-23 and 29</u> are subject to restriction and/or election requirement.</p> | | | | | |
| <p>Application Papers</p> <p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.</p> <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p> | | | | | |
| <p>Priority under 35 U.S.C. §§ 119 and 120</p> <p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <p style="margin-left: 20px;">1.<input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p style="margin-left: 20px;">2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p style="margin-left: 20px;">3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p> | | | | | |
| <p>Attachment(s)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> 1)<input type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. </td> <td style="width: 50%; vertical-align: top;"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____. </td> </tr> </table> | | | | 1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____. |
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____. | | | | |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-18-2002 has been entered.

The amendment filed on 4-18-2002 is acknowledged. Claims 1, 6 and 8-10 have been amended. Claim 7 has been canceled. Claims 1-6, 8-23 and 29 are currently pending. Claims 17-23 and 29 have been withdrawn from consideration. Claims 1-6 and 8-16 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 1-16 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of the amendment thereto and the cancellation of claim 7.

The rejection of claims 1-5, 11 and 14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the term “RIP60 activity” is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the term “under stringent conditions” is withdrawn in light of the amendment thereto.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by referring to sequences listed in Table 1 within the specification is withdrawn in light of the amendment thereto.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the phrase “nucleotides which are not identical to” is withdrawn in light of the amendment thereto.

The rejection of claims 6 and 9-10 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the term “unique fragments” is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 1-3, 6 and 8-9 under 35 U.S.C. 102(a) as being anticipated by Sulston et al. (Genome Research, Vol. 8 No. 11, 1998, pages 1097-1108) is maintained for reasons of record. Applicant's arguments will be addressed below.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-6 and 8-16 under 35 U.S.C. 103(a) as being unpatentable over Sulston et al. (Genome Research, Vol. 8 No. 11, 1998, pages 1097-1108) is maintained for reasons of record.

Applicant argues:

1. The cited reference does not disclose the claimed sequences.

2. The Genbank listing relied upon by Examiner has an availability date of 9-30-2000, which is after Applicant's priority date.
3. The Declaration by Nicholas H. Heintz sets forth proof that Applicants had conception and reduction to practice of the subject matter of the rejection prior to the publication date of the Sulstan GenBank submission in September 1998.

With regard to § 1.131 Affidavit or declaration of prior invention to overcome cited patent or publication, the MPEP states:

When any claim of an application or a patent under reexamination is rejected under 35 U.S.C. 102(a) or (e), or 35 U.S.C. 103 based on a U.S. patent to another or others which is prior art under 35 U.S.C. 102(a) or (e) and which substantially shows or describes but does not claim the same patentable invention, as defined in § 1.601(n), or on reference to a foreign patent or to a printed publication, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under § 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to overcome the patent or publication. The oath or declaration must include facts showing a completion of the invention in this country or in a NAFTA or WTO member country before the filing date of the application on which the U.S. patent issued, or before the date of the foreign patent, or before the date of the printed publication. When an appropriate oath or declaration is made, the patent or publication cited shall not bar the grant of a patent to the inventor or the confirmation of the patentability of the claims of the patent, unless the date of such patent or printed publication is more than one year prior to the date on which the inventor's or patent owner's application was filed in this country.

A date of completion of the invention may not be established under this section before December 8, 1993, in a NAFTA country, or before January 1, 1996, in a WTO member country other than a NAFTA country

The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. **Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained.**

Applicant has properly identified the date in question and has provided the required assertion that completion of the instant invention in a NAFTA or WTO member country. However, Applicant has failed to provide original exhibits as required. Applicant has provided sequences that constitute “results” and hence are insufficient to perfect the Declaration. Consequently, the rejection is maintained for reasons of record.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 1, SEQ ID NO:3, SEQ ID NO:5 and SEQ ID NO:50 which corresponds to the cDNA/genomic DNA encoding the protein human RIP60 and nucleic acids encoding polypeptides with sequences corresponding to SEQ ID NO: 2, SEQ ID NO:4, SEQ ID NO:6 and SEQ ID NO:51. Said sequences meet the written description provision of 35 USC 112, first paragraph. However, said claims are directed to encompass all nucleic acid fragments of the nucleic acid molecule of SEQ ID NO:1. None of these sequences meet the

written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Claims 6 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid comprising SEQ ID NO:1, does not reasonably provide enablement for nucleic acids comprising fragments of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification is silent on the use of said fragments. Additionally, the specification is silent on what properties said fragments need to possess in order to be used and how said fragments are to be used.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the

relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, not all are required to make a *prima facie* case. In the instant application since the breadth of claims encompass single nucleic acids or single amino acids, the amount of experimentation necessary to determine which fragments would possess the desired properties would be excessive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by reciting improper Markush language. It is unclear whether the claimed nucleic acid molecule comprises the nucleic acids of (a), (b) and (c).

Claim 6 and 9 are rendered vague and indefinite by the use of the term “fragment”. What is the lower limit of said term? 1 nucleotide? 1 codon?

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
June 28, 2002